

OCT 25 2000

RTek Medical Systems, LLC

K001295 Page 1 of 2

## **RTek Medical Systems, LLC**

16 Tobey Village Office Park  
Pittsford, New York 14534  
Tel: 716.249.0984 Fax: 716.383.1294

### **510(k) Summary**

[as required by 21 CFR section 807.92(c)]

Summary Prepared: April 20, 2000

Submitter's Name: RTek Medical Systems, LLC  
16 Tobey Village Office Park  
Pittsford, New York 14534

Contact: Robert C. Jackson, PhD  
President and Chief Executive Officer

Device Name: PIPER

Common Names: Brachytherapy Treatment Planning System  
Radiation Treatment Planning System

Classification: Class 2  
Product Code: 90MUJ

Device Name	Regulation
System, Planning, Radiation Therapy Treatment	21CFR Section 892.5050

Predicate Devices: The PIPER System is substantially equivalent to the following devices:

510(k) No.	Product Name	Manufacturer
K982821	MMS TherpacPlus B3DTUI	Multimedia Medical Systems
K982696	Interplant	Burdette Medical Systems
K982791	ROCS TPS	Radiation Oncology Computer Systems
K983343	Plato Brachytherapy (BPS v. 14.0)	Nucletron Corp.

### **510(k) Summary**

The RTek PIPER system for radiation treatment therapy planning is a microprocessor based device that when coupled with the appropriate accessories assists clinicians with the planning and evaluation of prostate brachytherapy procedures using permanent radioactive implants under ultrasound guidance.

The device has the same intended use as the legally marketed predicate devices.

The technological characteristics are the same or similar to those found with the predicate devices.

Verification, validation, and testing activities were conducted to establish the performance and reliability characteristics of the RTek device with respect to failure simulations and software functionality.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 25 2000

Robert C. Jackson, Ph.D.  
President/Chief Executive Officer  
RTek Medical Systems, LLC  
16 Tobey Village Office Park  
Pittsford, NY 14534

Re: K001295  
PIPER Radiation Treatment Therapy Planning System  
Dated: August 3, 2000  
Received: August 4, 2000  
Regulatory class: II  
21 CFR 892.5730/Procode: 90 MUJ

Dear Dr. Jackson:

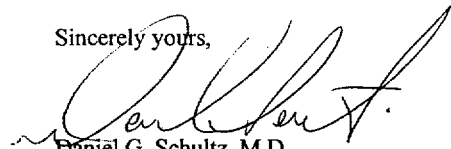
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.  
Captain, USPHS  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

**INDICATIONS FOR USE**Page 1 of 1510(k) Number (if known) K001295

Device Name: PIPER System

**Indications for Use:**

The RTek Medical Systems, PIPER system assists clinicians with the planning and evaluation of prostate brachytherapy procedures using permanent radioactive implants under ultrasound guidance. The PIPER System is intended for use by a competent health care professional such as a radiation oncologist, medical physicist, or radiation dosimetrist. Output from the PIPER system, in the form of displays, hardcopy prints and/or plots is provided to the health care professional for independent clinical review and judgement prior to use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Szymon  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices510(k) Number K001295Prescription Use X  
(Per 21 CFR 801.109)